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Long-term results of arterial allograft below-knee bypass grafts for limb salvage: A retrospective multicenter study

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Purpose: Arterial allografts (AAs) have been recently reconsidered in the treatment of critical limb ischemia when vein material is absent, because of the disappointing results with artificial grafts. The aim of this study was to report the results observed in three centers where AAs were used for infrainguinal reconstruction in limb-threatening ischemia.

Methods: Between 1991 and 1997, 165 AA bypass procedures were performed in 148 patients (male, 90) with a mean age of 70 years (range, 20-93 years). Indications for operation were rest pain in 54 cases and tissue loss in 111 cases. Mean resting ankle pressure was 53 mm Hg in 96 patients who did not have diabetes and mean transcutaneous pressure of oxygen was 10 mm Hg in 52 patients who did have diabetes. In 123 cases (75%), there was at least one previous revascularization on the same limb. AAs were obtained from cadaveric donors. The distal anastomosis was to the below-knee popliteal artery in 34 cases, to a tibial artery in 114 cases, and to a pedal artery in 17 cases.

Results: At 30 days, the mortality rate was 3.4%; the primary patency rate was 83.3%; the secondary patency rate was 90%; and the limb salvage rate was 98%. During follow-up (mean, 31 months), 65 grafts failed primarily. Causes of primary failure were thought to be progression of the distal disease in 15 cases, myointimal hyperplasia in 16 cases, graft degradation in 10 cases (four dilations, three stenoses, two ruptures, and one dissection), miscellaneous in eight cases, and not known in 16 cases. Primary patency rates at 1, 3, and 5 years were, respectively, 48.7% ± 4%, 34.9% ± 6%, and 16.1% ± 7%. Secondary patency rates at 1, 3, and 5 years were, respectively, 59.8% ± 4%, 42.1% ± 5%, and 25.9% ± 8%. Limb salvage rates at 1, 3, and 5 years were, respectively, 83.8% ± 3%, 76.4% ± 5%, and 74.2 % ± 8%.

Conclusion: AA leads to an acceptable limb salvage rate but poor patency rates. A randomized trial that will compare AAs and polytetrafluoroethylene should be undertaken. (J Vasc Surg 2000;31:426-35.)

Long-term results of infrainguinal bypass grafts for limb-threatening ischemia in the absence of autologous saphenous vein are poor. New graft materials and techniques have been used in an attempt to improve the results.[1-6] However, reported patency and limb salvage rates are still lower than those obtained with autologous saphenous vein.

Arterial allografts (AAs) were widely used in the 1950s.[7] They were soon abandoned for prosthetic grafts because of low patency rates and frequent aneurysmal degeneration.[8,9] Since then, tissue preservation techniques have improved, with new preservation media and cryopreservation being now available. For these reasons, AAs were recently reconsidered in two indications: prosthetic graft infection[10] and limb salvage. Previous reports on the results of AA bypass grafts for critical ischemia studied small groups of patients with a short-term follow-up.[11-13] The aim of this study was to assess

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Competition of interest: nil.

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Table I. Risk factors and major comorbidities

	N	%
Risk factor		
Tobacco use	46	31
Diabetes	52	35
Hypertension	96	65
Hyperlipidemia	20	13
Comorbidity		
Cardiac disease	59	40
Renal failure	26	18

Table II. Site of proximal and distal anastomosis

Site	*N*
Proximal anastomosis	
Iliac artery	16
Common femoral artery	106
Superficial femoral artery	38
Above-knee popliteal artery	1
Below-knee popliteal artery	4
Distal anastomosis	
Below-knee popliteal artery	34
Tibioperoneal trunk	10
Anterior tibial artery	40
Posterior tibial artery	25
Peroneal artery	39
Pedal artery	17

long-term results of AAs in patients with limb-threatening ischemia.

METHODS

Patients. Between April 1991 and June 1997, 148 patients from three centers underwent 165 AA bypass grafts. Patient distribution among the three centers (A, B, and C) was, respectively, 73, 46, and 29 patients. There were 90 male patients and 58 female patients. The mean age was 70 years (range, 20-93 years). The risk factors and major comorbidities are shown in Table I. The indications for operation were rest pain in 54 cases, minor tissue loss in 94 cases, and major tissue loss in 17 cases. Patients with acute ischemia were excluded from the study. Mean resting ankle pressure was 53 mm Hg (range, 0-140 mm Hg) in patients who did not have diabetes. Patients with diabetes had a mean transcutaneous oxygen pressure of 10 mm Hg (range, 0-30 mm Hg). All patients underwent preoperative angiography. Run-off scores were calculated as recommended by the Ad Hoc committee on Reporting Standards.[14] The mean score was 5.5 (range, 1-10). For 45 revascularizations (27%), the score was equal or greater than 8. In 123 cases (75%), there was at least one previous revascularization on the same limb and, in 41 cases (25%), at least two previous revascularizations. AA was indicated in 127 cases because of the absence of greater saphenous vein and in 38 cases because of its unsuitability (dilation, small size, calcifications). ABO matching was not achieved in 21 cases because no matching graft was available. The surgeon felt that the potential benefit for the patient was greater than the risk of having a complication from an ABO mismatch. The site of the distal and proximal anastomosis are shown in Table II. Thirty-one bypass grafts were composite. In 14 cases a combination graft with polytetrafluoroethylene (PTFE) for the proximal anastomosis was used because the AA was too short. In 16 cases a combination with a piece of saphenous vein for the distal anastomosis was used because of the caliber discrepancy between the AA and a small tibial vessel. A combination graft with both PTFE and saphenous vein was used in one case. Seventeen bypass grafts were sequential. The intermediate patent segment was the popliteal artery in eight cases, the superficial femoral artery in two cases, the deep femoral artery in two cases, and a tibial artery in five cases. There were 153 first AA bypass grafts and 12 second AA bypass grafts, the latter being performed because of failure of previous AA bypass graft. Intravenous heparin was administered the first days after operation. Patients were eventually given antiplatelet drugs in 41 cases, oral anticoagulants in 37 cases, and antiplatelet drugs plus oral anticoagulants in 87 cases.

Arterial allografts processing. AAs were harvested from brain-dead donors as part of the multiple-organ harvesting program. Donors were screened for hepatitis B and C virus, human immunodeficiency virus, and cytomegalovirus. If one of the tests was positive, the patient did not undergo harvesting. Surgical, atraumatic harvesting involved descending thoracic aorta and arteries of the limbs from the aortic bifurcation to the tibioperoneal trunk. Then, AAs were placed in sterile preservation medium with added antibiotics and fungicides. Fresh allografts (n = 45) were used at the beginning of this experience when cryopreservation techniques had not been applied to AAs. They were kept sterile at 4°C in the initial medium until the revascularization was performed. The mean delay between harvesting and grafting was 14 days; the maximum delay was 40 days.

Cryopreserved AAs were processed within 48 hours after harvest. Before that, samples for bacteriologic analysis were collected from the initial preservation medium. AAs were put in freezing bags

Fig 1. Completion angiogram of a femoroposterior tibial AA bypass grafting.

(Hemofreeze bag; NBPI, Emmer-compascuum, The Netherlands), and dimethyl sulfoxide was added. AAs were then frozen progressively in a Digitcool device (Cryo Bio System, L'aigle, France), with a programmed decreasing rate in temperature. They were stored in nitrogen vapor between –120°C and –150°C. The composition of initial preservation medium and cryopreservation protocol used in the three centers are summarized in Table III. AAs were discarded in the case of positive bacterial culture. For cryopreserved AAs, a minimal delay of 4 months was allowed before the graft was used. Thus it was possible to look for seroconversion in recipients of the organs harvested from the same donor. If seroconversion was found, corresponding AAs were discarded. When the use of an AA for a patient was decided, the freezing bag was placed in a water bath at 37°C to thaw. AAs were not manipulated until totally thawed to avoid fractures. A new sample for bacterial analysis was performed once the bag was opened. Collateral branches of the graft were ligated with 6-0 polypropylene sutures. The standard infrainguinal bypass grafting procedure was performed.

Follow-up. At the beginning of the study period, an invasive follow-up was performed in the center that started this technique. At 3 months, angiography (Fig 1) and biopsy under local anesthesia were performed to detect rejection or morphologic changes of the allograft. In the other two centers, duplex scan was performed after the operation at 3, 6, and 12 months and yearly thereafter. When the graft was patent, anomalies seen either on duplex scan or angiography were considered to be a failure only if they required an intervention. Primary patency curves were established, with those failures considered occlusions. Anomaly of the allograft was defined as follows: stenosis of proximal or distal anastomosis, graft dilation, graft rupture, mid-graft stenosis (as opposed to anastomotic stenosis), graft dissection, or adherent thrombus. Graft degradation was defined as an alteration of the structure of the graft (excluding the anastomosis) that occurred during follow-up and included dilation, rupture, stenosis, and dissection. For dilations and stenoses, the following criteria assessed by duplex scan and / or angiography prompted revision of the graft: dilation greater than 50% of the artery diameter immediately above the dilated segment; stenosis of 60% to 70% or greater.

Statistical analysis. Cumulative primary and secondary patency, limb salvage, and survival rates were assessed with the use of the life-table method. Comparison of estimates was performed with the log-rank test.

RESULTS

Postoperative results. Five patients (3.4%) died during the 30-day postoperative period: two patients had myocardial infarction, and one patient had stroke. One patient had preoperative anemia as the result of renal failure. She had a long procedure that resulted in significant worsening of the anemia and subse-

Table III. Composition of the initial preservation medium and cryopreservation protocol in the three centers

	Center A	*Center B*	*Center C*
Initial preservation medium	Eurocollins[17] Gentamicin 240 mg/L Colistin 10^5 U/L Lincomycine 100 mg/L	Belzer[16] Gentamicin 240 mg/L Colistin 10^6 U/L Lincomycine 400 mg/L	RPMI 1640[15] Gentamicin 20 mg/L Metronidazole 500 mg/L Cefuroxime 750 mg/L Amphotericin B 50 mg/L Hepes 5 10^{-4} mol/L Heparin 7500 U/L 20% Human albumin 2.5 mL
Cryopreservation protocol			
Storage temperature (°C)	–120	–150	–160
DMSO concentration (%)	15	15	10

DMSO, Dimethyl sulfoxide.

quently experienced cardiac failure. The cause of death was not known for the last patient, aged 88 years, who had poor general condition and who died after an above-knee amputation. None of these deaths were related to a specific complication of the AA. Thirty grafts failed after the operation. Twenty-eight grafts occluded; one patient had worsening tissue loss despite graft patency, and one patient had a thrombus (seen on postoperative duplex scan) that required subsequent revision. Causes for occlusion were thought to be poor run-off in 16 cases, technical error in 3 cases, graft stenosis in 1 case, low-flow state in 1 case, sudden interruption of anticoagulant treatment in 1 case, and unknown in 6 cases. The patient underwent surgical revision in 14 cases and a redo procedure in one case (ie, the allograft was removed, and a new AA bypass grafting was performed); the 13 remaining patients had no further procedure. Amputation was required in five cases. Primary and secondary patency and limb salvage rates at 1 month were 83.3%, 90%, and 98%, respectively.

Late results. Mean follow-up was 31 months (range, 1-81 months). Sixty-one patients died during follow-up. Long-term survival rates are shown in Fig 2. In 12 cases (7.3%), a complete surveillance program could not be achieved, and patients were considered lost to follow-up for patency at the date of their last duplex scan. We observed 65 primary failures (48%): 56 occlusions, 5 stenoses of the distal anastomosis, 1 stenosis of the graft, 2 dilations, and 1 rupture. Causes of primary failure are reported in Table IV. One patient who had a ruptured allograft subsequently died of hemorrhage before surgery could be attempted. Among patients from the "miscellaneous" group, two patients had sudden interruption of anticoagulant treatment; one patient had constitutional deficit in S protein; one patient experienced the development of stenosis of the external iliac artery, which was dilated; and one patient had open ankle dislocation (this patient experienced the development of extensive necrosis of the wound, and the limb had to be amputated although the bypass graft was patent). Finally, 15% of late primary failures (10/65 failures) were due to graft degradation, whereas 48% of late primary failures (31/65 failures) were due to either progression of distal disease or myointimal hyperplasia.

Table IV. Causes of late primary failures

Cause	*N*
Myointimal hyperplasia	16
Progression of distal disease	15
Graft degradations	
Aneurysm	4
Stenosis	3
Rupture	2
Dissection	1
Miscellaneous	
Anticoagulation	3
Low flow states	2
External compression	1
Inflow disease	1
Limb injury	1
Unknown	16
TOTAL	65

Forty-one grafts had further procedures after primary failure. Thirty-five grafts were surgically revised, and two grafts had thrombolysis. In four cases, a new AA bypass graft was performed. Twenty-four grafts had no further procedure after primary failure. After secondary procedure, 23 grafts occluded again, five of which were replaced by a new allograft. Major amputation was required for 25 limbs. Another six grafts had moderate dilations (ie, less than 50% of the diameter of the graft above the dilation), and two grafts had moderate stenosis of the distal anastomosis (less than 60%). They did not require an intervention and

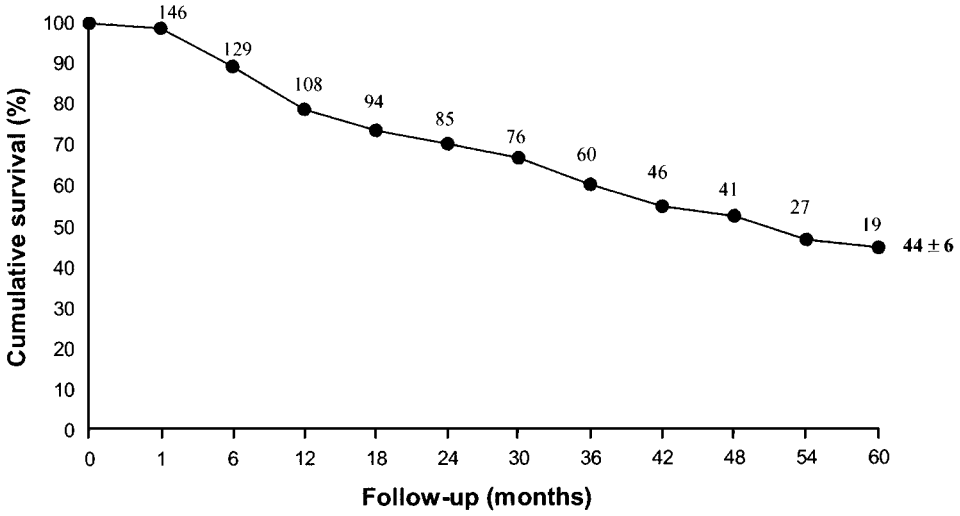


Fig 2. Life-table analysis for survival. The figure above each plot point indicates the number of patients at risk at the beginning of the interval. The figure on the right (*44* ± *6*) indicates the cumulative survival at 5 years ± SE.

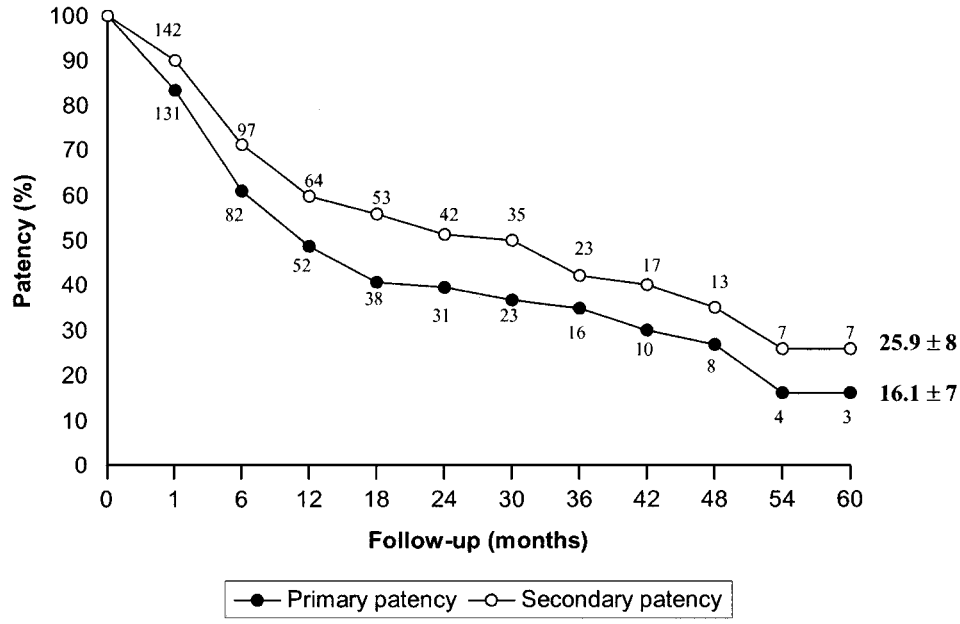


Fig 3. Life-table analysis for primary and secondary patency. The figure above each plot point indicates the number of grafts at risk at the beginning of the interval. The figures on the right indicate cumulative primary and secondary patency at 5 years ± SE.

were followed up. No adverse event as the result of the systematic sampling was observed.

Primary patency rates at 1, 3, and 5 years were 48.7% ± 4%, 34.9% ± 6%, and 16.1% ± 7% (Fig 3). Secondary patency rates at 1, 3, and 5 years were 59.8% ± 4%, 42.1% ± 5%, and 25.9% ± 8% (Fig 3). Limb salvage rates at 1, 3, and 5 years were 83.8% ± 3%, 76.4% ± 5%, and 74.2 ± 8% (Fig 4). Comparisons of patency rate according to secondary variables are shown in Table V. Primary and secondary patency

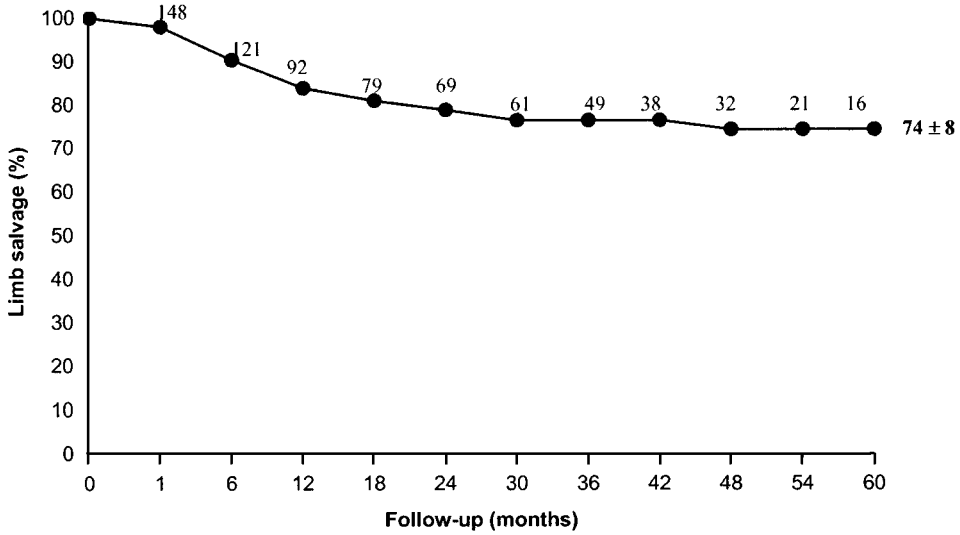


Fig 4. Life-table analysis for limb salvage in the whole series. The figure above each plot point indicates the number of limbs at risk at the beginning of the interval. The figure on the right indicates the cumulative limb salvage at 5 years ± SE.

Table V. Comparison of patency rates according to secondary variables with the log-rank test

Secondary variable	*Log-rank value*	*P value*
ABO matching (yes vs no)	0.265	>.05
Preservation (fresh vs cryopreservation)	0.265	>.05
Center (A vs B)	0.088	>.05
Center (B vs C)	0.087	>.05
Center (C vs A)	0.238	>.05
Previous interventions (none vs one or more)	0.340	>.05
Site of distal anastomosis (below-knee vs infrapopliteal)	0.885	>.05
Run-off score (<5 vs ≥5)	0.808	>.05
Composite (yes vs no)	0.145	>.05
Sequential (yes vs no)	0.095	>.05
Anticoagulant protocol (AP vs OA)	0.028	>.05
Anticoagulant protocol (AP vs OA+AP)	0.521	>.05
Anticoagulant protocol (OA vs OA+AP)	0.398	>.05
Secondary intervention (yes vs no)	0.524	>.05

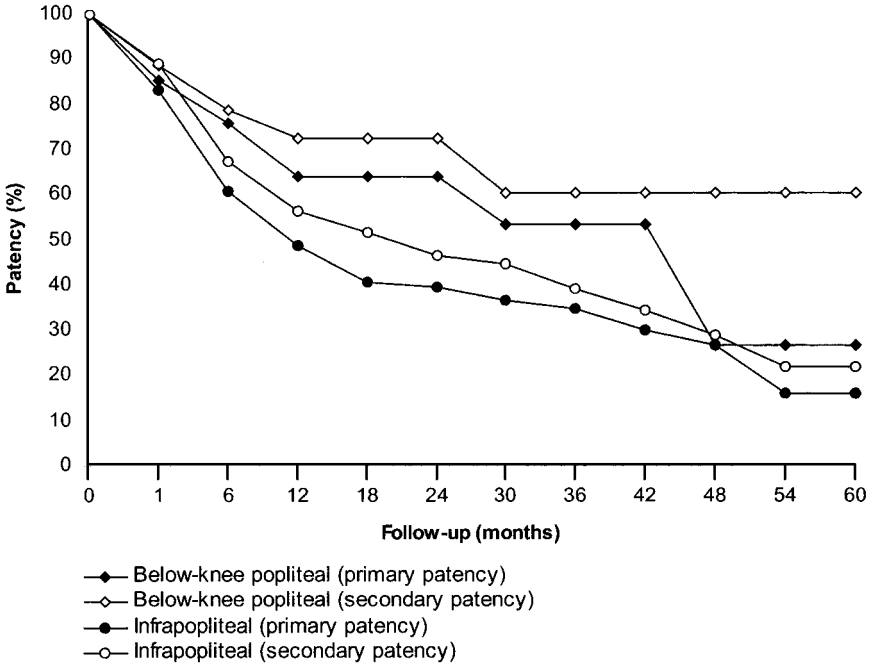
AP, Antiplatelet therapy; *OA*, oral anticoagulant.

rates of below-knee and infrapopliteal AA are shown in Fig 5.

Pathologic examination. Fourteen pathology reports of AA samples (obtained 3 months or more after implantation) were available for analysis. In five cases systematic biopsies were performed at 6 months. Four AAs were explanted because of graft degradation (three dilations and one dissection). The remaining five samples were obtained during secondary procedures for graft occlusion. Lymphomonocytic infiltration was found in five cases. From these five AAs, only one had graft degradation (ie, dissection). In most of cases, endothelial and smooth muscle cells were absent, with marked medial fibrosis.

DISCUSSION

The allograft degradation rate leading to primary failure in this study was about 3%. This is lower than reported earlier.[8,9] Several reasons might explain this difference. New preservation media[15-17] may cause less damage to AAs than the ones used in the 1950s. Use of cryoprotectant solution and controlled freez-



	1 year	3 years	5 years
BK popliteal primary patency	**71 ± 9** (14)	**50 ± 13** (4)	**25 ± 22** (1)
BK popliteal secondary patency	**74 ± 8** (14)	**57 ± 14** (4)	**57 ± 37** (1)
Infrapopliteal primary patency	**43 ± 4** (62)	**31 ± 7** (16)	**14 ± 8** (3)
Infrapopliteal secondary patency	**56 ± 4** (75)	**39 ± 6** (26)	**22 ± 9** (5)

Fig 5. Separate life-table analysis for primary and secondary patency of below-knee (*BK*) and infrapopliteal bypass grafts. The figures (*bold type*) in the table are cumulative patency rates ± SE, and the figures in parentheses indicate the number of grafts at risk at the beginning of the interval.

Table VI. Primary patency of infrapopliteal PTFE bypass grafts without adjunctive procedures

		Primary patency (%)				
Study	*Year*	*1 yr*	*2 yr*	*3 yr*	*4 yr*	*5 yr*
Fichelle et al[29]	1995	61	48	43	42	—
Parsons et al[30]	1996	71	47	39	36	28
Schweiger et al[31]	1993	51	46	37	31	—
Davies et al[32]	1991	37	33	31	25	22
Veith et al[33]	1986	46	34	30	12	—
Rafferty et al[34]	1987	31	21	19	17	14

ing rate are important improvements that prevent cell damage during freezing. Bench test studies have shown preservation of mechanical properties after cryopreservation.[18,19] Several studies have shown the preservation of endothelial and smooth muscle cells properties (contractile activity, endothelium-dependent and independent relaxation) of AAs after cryopreservation.[20,21] The incidence of graft rupture was 1.2% (2 / 165 grafts), which suggests that this condition is unusual. However, one of the two patients died of this complication. This is a severe condition; and if more of these should arise in the future, the technique should certainly be abandoned. Graft dilation did not cause death to our knowledge but was responsible for redo procedures. These shortcomings do not exist with prosthetic grafts. However, infec-

Table VII. Primary patency of infrapopliteal PTFE bypass grafts plus adjunctive procedures (cuff, patch, arteriovenous [A-V] fistulas)

Type of adjunctive procedure	*Study*	*Primary patency (%)*					
		Year	*1 yr*	*2 yr*	*3 yr*	*4 yr*	*5 yr*
Cuff ± A-V fistula	Wijesinghe et al[35]	1998	64	51	—	—	—
	Morris et al[36*]	1993	29	29	27	23	—
	Morris et al[36†]	1993	25	20	17	14	—
	Harris et al[37]	1993	61	61	—	—	—
A-V fistula	Ascer et al[1‡]	1996	78	70	61	—	—
Patch	Taylor et al[4]	1992	74	—	58	—	54
	Fichelle et al[29]	1995	—	—	45	—	—

*Primary procedures.
†Secondary procedures.
‡Assisted primary patency.

tion of a prosthetic graft can lead to dramatic complications, in which severity may be similar to arterial allograft rupture. Indeed, incidence of femoro-distal bypass graft infection can be up to 3%, with mortality rates up to 27%.[22] There was no case of graft infection in this series, and clinical and experimental data[10,23,24] show that AAs are more resistant to infection than prosthetic grafts. Whether the incidence of severe graft complications is lower when a PTFE graft is used in this population of patients still has to be proved.

There have been some controversies about what type of preservation (ie, fresh or cryopreservation) should be used. The important advantage of cryopreserved AA is a better protection against infection transmission. Longer storage periods allow a time interval for viral screening of other recipients and, if positive, to discard corresponding AA. For this reason, we think it is no longer ethical to use fresh allografts. The problem of protection against prions is a real concern and is not solved yet because of very limited knowledge of the disease.

It is likely that immunologic rejection of AA exists. Pathologic examination of explanted AAs in this study favor this hypothesis: lymphocyte infiltration of the media and the adventitia have been found. Absence of endothelium and fibrosis of the media were the most common pathologic features. They are similar to those shown in experimental rat models of AA immunologic rejection.[25,26] However, we do not know the incidence and the clinical significance (ie, graft degradation and graft occlusion) of the rejection phenomenon. No difference was found when patency rates were compared according to ABO matching (Table V). There was no graft degradation in the non-matched ABO group. These data suggest that ABO matching does not play an important role in the maintenance of patency and avoidance of degradation. Encouraging results have been obtained with AAs in patients who receive immunosuppressive treatment after kidney transplantation,[12] but this series included only 13 patients with short-term follow-up. Patients were not given immunosuppressive drugs in this study for the following reasons: toxicity of available drugs (especially renal toxicity with cyclosporin) would not be tolerated in older patients with poor general condition; risk of infection in patients with tissue loss would be high; in randomized trials, immunosuppressive drugs have failed to improve patency and limb salvage rates with cryopreserved venous allografts[27]; and the cost / benefit ratio was likely to be high for patients with low life expectancy.

Although postoperative patency rates were good, late patency rates were poor. Good early results can be explained by the fact that AAs are easy to handle. Indeed, elastic properties close to those of a normal artery and caliber consistency with small tibial arteries facilitated the realization of the distal anastomosis. Forty-eight percent of late primary failures were due to either progression of distal disease or myointimal hyperplasia, whereas only 15% were due to graft degradation. The progression of distal disease and myointimal hyperplasia have been described to be the main causes of failure of PTFE grafts.[28] These data suggest that the potential advantage of AAs over PTFE grafts would be to decrease the incidence of early failure caused by technical problems. In the long-term, AAs seem to behave the same as PTFE grafts, because their causes of failure are similar.

There was an important discrepancy between poor late patency and acceptable limb salvage rates. At least two explanations can be given. Some patients may have healed, or rest pain would have settled without operation. It is difficult to predict which patients will have this spontaneous favorable outcome, on clinical grounds and with the noninvasive techniques currently available. Collateral circulation, which developed although the bypass graft was patent, might have provided sufficient blood supply to avoid the recurrence of symptoms when the bypass graft occluded.

A number of secondary variables concerned the different practices that existed in each center (ie, preservation protocol, postoperative anticoagulant treatment, follow-up protocol) and the different types of grafts (ie, composite, sequential). Because this was a retrospective study, there was no standardization of the methods between centers. However, a comparison of patency rates according to these variables was not significant (Table V), which suggests that there may be other determinants for patency and degradation.

Patency rates obtained with AA were clearly worse than those obtained with autologous saphenous vein. But the comparison was not as easy with prosthetic grafts. Table VI and VII show primary patency rates of infrapopliteal bypass grafts for limb salvage obtained with PTFE grafts alone or with adjunctive procedures. The range of reported patency rates was considerably wide. For example, primary patency rates at 3 years varied from 17% to 61%. The primary patency rate at 3 years obtained with infrapopliteal AA bypass grafts was 31%. Clearly, reported patency rates for PTFE grafts were either worse, equal, or better than patency rates of AAs in this study. Furthermore, the discrepancy between reported patencies may be explained by differences other than the surgical technique itself, such as risk factors, comorbidities, and severity of the disease. Because the patients in this study had very advanced disease (with high run-off scores and high incidence of comorbidities) and most of them had several procedures before the allograft, the results achieved with PTFE grafts might have been worse. The answer to that question is critical because better results would justify further use of AAs for these patients. The solution of the problem is not given by these data; only a randomized trial would allow a comparison of the performance of AAs and prosthetic grafts. It would also allow a comparison of the incidence of graft-related complications in the two techniques.

CONCLUSION

This study shows that AA infrainguinal bypass grafts for critical ischemia leads to acceptable limb salvage but poor patency rates. A randomized trial would allow accurate comparison between AAs and PTFE grafts. Only better results would justify further clinical use of AAs. It seems possible to decrease the incidence of degradations by an improvement of harvesting and preservation techniques and in our understanding of host-graft interactions. Experimental investigations on that subject are to be continued.

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